

Appn. No.: 10/673,000  
Amendment Dated: March 25, 2008  
Reply to Office Action of January 9, 2008

UOD-154US1

**Remarks/Arguments:**

This amendment is in response to the Office Action dated January 9, 2008.

Claims 1 and 7 are amended to state that the sample is substantially free of a denaturing agent. By this amendment, the added terms rejected by the Office Action under 35 USC Section 112 have been removed and language suggested in the Office Action has been added. Support for this amendment may be found in the specification in paragraphs 0014, 0018, 0029, and 0037. This amendment differentiates the invention from the procedure disclosed by Gorvits and Horowitz, which employs high concentrations of the denaturing agent, urea.

Claims 1 and 7 are further amended to state that the protein refolding step does not encompass repeated cycling between ambient and elevated pressure. Support for this amendment is found at paragraphs 0041 and Examples 2, 5, 6, and 8, which describe application and release of high hydrostatic pressure, but not cycling between high and low pressure.

Claims 19 and 20, which are rejected by the Office Action under 35 USC Section 112, have been cancelled.

Pending claims 1-12 are rejected under 35 USC Section 102(e) as anticipated by Litt, U.S. Patent No. 6,635,469. Litt's method differs from that claimed by Applicants in that cycling between high and low pressure is required to bring about protein refolding. Litt discusses a process to refold protein from denatured protein aggregates at column 9, line 15. Aggregates of denatured protein are subjected to elevated pressure to form denatured protein chains and subsequently the pressure is *rapidly cycled* to cause denatured polypeptides to fold properly (Col. 9, lines 17-25). Cycling of the pressure is required for refolding of the protein in Litt's process (Col. 18, lines 8-11). No examples demonstrating disaggregation and refolding of protein aggregates in the absence of pressure cycling are presented in Litt. Litt does not disclose disaggregation and refolding of protein in the absence of pressure cycling and, therefore, does not anticipate Applicants' claimed invention.

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To distinguish their procedure from Litt, Applicants have amended claims 1 and 7 to state that pressure is not cycled between elevated and ambient pressures during the protein refolding step. Although this limitation is not described in these specific words in Applicants' specification, lack of literal basis in the specification for a negative limitation is not necessarily sufficient to establish lack of descriptive support. *Ex parte Parks*, 30 USPQ2d 1234, 1236 (BPAI 1993); MPEP 2173.05(i). "Adequate description under the first paragraph of 35 USC 112 does not require *literal* support for the claimed invention. Rather, it is sufficient if the originally-filed disclosure would have conveyed to one having ordinary skill in the art that an appellant had possession of the concept of what is claimed." *Id.*, citations omitted. See also MPEP 2163.02. One of ordinary skill in the art would understand from Applicants' description and explicit examples that Applicants' claimed method does not encompass a step of "cycling between low and high hydrostatic pressure" or "rapidly cycling the pressure" to bring about protein refolding as required by the method of Litt (Litt, Col. 9, lines 20-21; Col. 18, lines 8-9). Accordingly, Applicants submit that the pending claims are in condition for allowance.

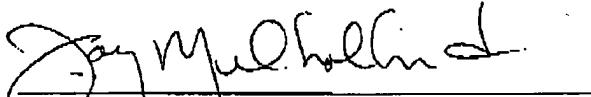
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**Conclusion**

It is respectfully submitted that the claims are in condition for immediate allowance and a notice to this effect is solicited. The Examiner is invited to phone applicants' attorney if it is believed that a telephonic interview would expedite prosecution of the application.

Respectfully submitted,



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March 25, 2008

